Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Registration: Navinta LLC

[Docket No. DEA-392]

ACTION: Notice of registration.

SUMMARY: Navinta LLC applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Navinta LLC registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated February 11, 2015, and published in the *Federal Register* on February 19, 2015, 80 FR 8901, Navinta LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Navinta LLC to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled Substance	Schedule
Pentobarbital (2270)	II
Remifentanil (9739)	II

The company plans to initially manufacture API quantities of the listed controlled substances for validation purposes and FDA approval, and then produce commercial size batches for distribution to dosage form manufacturers upon FDA approval.

Dated: July 10, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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